

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

3B MEDICAL, INC.,

Plaintiff,

-v.-

SOCLEAN, INC.,

Defendant.

19 Civ. 3545 (KPF)

**OPINION AND ORDER**

KATHERINE POLK FAILLA, District Judge:

Plaintiff 3B Medical, Inc. manufactures a suite of devices that automatically sanitize continuous positive airway pressure (“CPAP”) machines using UV-C light. Plaintiff brings this action against Defendant SoClean, Inc., a competitor that manufactures similar devices, albeit with the distinction that Defendant’s devices use ozone as a sanitizing agent. Plaintiff alleges that Defendant has relied on false and misleading representations to consumers relating to Defendant’s devices’ use of ozone and the safety of said use, in violation of the Lanham Act, 15 U.S.C. § 1125(a), as well as various state-law claims. Defendant, in turn, has filed the instant motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Plaintiff has failed to state a claim upon which relief may be granted. For the reasons set forth below, the Court finds that Plaintiff has indeed failed to state a claim because of deficiencies in pleading injury, and therefore grants Defendant’s motion to dismiss.

## **BACKGROUND<sup>1</sup>**

### **A. Factual Background**

#### **1. The Parties**

Plaintiff is a Florida corporation with its principal place of business in Winter Haven, Florida. (Compl. ¶ 6). Since 2018 (*see* Galgay Decl., Ex. 1),<sup>2</sup> Plaintiff has produced and sold the Lumin and the Lumin Bullet, both of which are designed for individuals who suffer from sleep apnea (Compl. ¶ 12). Specifically, the Lumin and the Lumin Bullet use a UV-C light source to sanitize and disinfect CPAP equipment. (*Id.* at ¶¶ 22-23). Defendant — a Delaware corporation with its principal place of business in Peterborough, New Hampshire — offers competing products. (*Id.* at ¶¶ 7, 11). Unlike Plaintiff’s devices, Defendant’s SoClean devices use ozone gas to clean CPAP equipment. (*Id.* at ¶ 25). Defendant’s devices have been on the market since at least 2012. (*Id.* at ¶ 2). Defendant commands 90% of the market for CPAP machine cleaners, while Plaintiff holds only 5%. (*Id.* at ¶¶ 159-60). The other 5% is controlled by three other competitors — Sleep8, VirtuClean, and Respify — all

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<sup>1</sup> The Court draws the facts for this Opinion from the Amended Complaint (the “Complaint” or “Compl.” (Dkt. #42)), which is the operative pleading in this action, as well as certain exhibits to the Declaration of Clancy Galgay in Support of Defendant SoClean’s Motion to Dismiss (“Galgay Decl., Ex. [ ]” (Dkt. #47)).

For ease of reference, the Court refers to Defendant’s opening brief as “Def. Br.” (Dkt. #48); Plaintiff’s opposition brief as “Pl. Opp.” (Dkt. #53); and Defendant’s reply brief as “Def. Reply” (Dkt. #54). The Court does not reference Plaintiff’s sur-reply (Dkt. #62), as it does not contain briefing relevant to the dispositive issue in this Opinion.

<sup>2</sup> The Court finds it proper to take judicial notice of Plaintiff’s own press release and its announcement of the Lumin’s entry into the market. (Galgay Decl., Ex. 1). Plaintiff does not dispute the timing of its entry into the market, and Plaintiff’s own press release is a source whose accuracy as to the date of Lumin’s entry into the market cannot reasonably be questioned. *See* Fed. R. Evid. 201(b).

of which use ozone as well. (*Id.* at ¶¶ 161-62). Both parties' devices are offered to consumers as an alternative to handwashing their CPAP equipment. (*Id.* at ¶ 22).

## **2. The Alleged Misrepresentations**

All of Defendant's devices use ozone as the primary sanitizing agent. (Compl. ¶ 25). Ozone is a toxic gas that can have a variety of serious health consequences to humans when inhaled. (*Id.* at ¶¶ 33, 47-56). Defendant's devices produce ozone at concentrations well above the limits allowed by the Food and Drug Administration (the "FDA"). (*Id.* at ¶¶ 37-38, 87-90, 97).

Plaintiff alleges that Defendant's marketing materials contain a host of misrepresentations that are designed both to obscure Defendant's use of ozone as a sanitizing agent and to mislead consumers about the health risks posed by Defendant's use of ozone. (*See* Compl. ¶ 3). Plaintiff points in particular to six different misrepresentations that have appeared in various SoClean marketing materials since at least 2012. (*Id.* at ¶¶ 101-45, 148). Those misrepresentations include the following:

- Defendant's marketing materials represent that its devices use "activated oxygen," instead of ozone (*id.* at ¶ 108);
- Defendant's marketing materials represent that its devices do not use "chemicals" or "harsh chemicals" (*id.* at ¶ 118);

- Defendant markets its devices as “safe” and “healthy” (*id.* at ¶ 122);
- Defendant represents that its devices use the same sanitizing process as that used in hospitals (*id.* at ¶ 128);
- Defendant represents that the charcoal filter cartridges that accompany its devices are able to convert “activated oxygen” into “regular oxygen” (*id.* at ¶ 139); and
- Defendant represents that its devices are closed-loop systems, out of which no “activated oxygen” escapes (*id.* at ¶ 144).

Plaintiff alleges that consumers have reported adverse experiences with Defendant’s devices due to the devices’ use of ozone. (Compl. ¶ 156).

Moreover, some consumers have reported that they decided to purchase the Lumin specifically because it does not use ozone. (*Id.* at ¶ 169). Based on the above, Plaintiff alleges that more consumers would learn of, and purchase, its products if not for Defendant’s false advertising. (*Id.* at ¶¶ 170-72).

## **B. Procedural Background**

Plaintiff initiated this action with the filing of a complaint on April 22, 2019. (Dkt. #1). On June 12, 2019, Defendant filed a letter with the Court requesting a conference to discuss an anticipated motion to dismiss. (Dkt. #20). Plaintiff responded on June 17, 2019 (Dkt. #22), and the Court set a pre-

motion conference for August 27, 2019 (Dkt. #23). At the August 27, 2019 conference, the Court permitted Plaintiff to file an amended complaint and scheduled briefing for Defendant's motion to dismiss. (Minute Entry for August 27, 2019).

On September 16, 2019, Plaintiff filed the Complaint, alleging violations of the Lanham Act, 15 U.S.C. § 1125(a); New York General Business Law ("GBL") Sections 349 and 350; and a common-law claim for unfair competition. (Dkt. #42). Defendant filed its motion to dismiss, along with an accompanying memorandum and declaration, on October 25, 2019. (Dkt. #46-48). Defendant also requested that the Court schedule oral argument on the motion, and the Court indicated that it would schedule oral argument if it believed it to be necessary. (Dkt. #49-50). On December 2, 2019, Plaintiff filed its opposition brief. (Dkt. #53). On December 16, 2019, Defendant filed its reply brief. (Dkt. #54).

On the same day that Plaintiff filed its opposition brief, it informed the Court that it believed one of Defendant's exhibits — specifically, a user manual for a SoClean device — to have been falsified. (Dkt. #51). On January 14, 2020, Plaintiff filed a letter requesting a conference to discuss an anticipated motion for sanctions in regards to the allegedly falsified exhibit. (Dkt. #55). Defendant responded to Plaintiff's letter on January 17, 2020 (Dkt. #56), and the Court in turn scheduled a pre-motion conference for February 18, 2020 (Dkt. #57). At the February 18, 2020 conference, the Court expressed its belief that a motion for sanctions would not be successful. (Dkt. #63). However, the

Court permitted Plaintiff to file a sur-reply so that it could address the ways in which it believed Defendant's conduct had affected the briefing for the motion to dismiss. (*Id.*). On March 3, 2020, Plaintiff filed its sur-reply, closing the briefing for the instant motion. (Dkt. #62). The motion being fully briefed, and the Court finding that it can decide the motion on the papers, the Court now proceeds to the substance of this Opinion.

## **DISCUSSION**

### **The Court Grants Defendant's Motion to Dismiss**

#### **A. Motions to Dismiss Under Fed. R. Civ. P. 12(b)(6)**

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must “draw all reasonable inferences in Plaintiff's favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief.” *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” (internal quotation marks omitted)). A plaintiff is entitled to relief if he alleges “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007) (“While *Twombly* does not require heightened fact pleading of specifics, it does require enough facts to nudge plaintiff's claims

across the line from conceivable to plausible.” (internal quotation marks omitted) (citing *Twombly*, 550 U.S. at 570)).

That said, a court is not bound to accept “conclusory allegations or legal conclusions masquerading as factual conclusions.” *Rolon v. Henneman*, 517 F.3d 140, 149 (2d Cir. 2008) (internal quotation marks omitted) (quoting *Smith v. Local 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir. 2002)); see also *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (“[A]lthough a court must accept as true all of the allegations contained in a complaint, that tenet is inapplicable to legal conclusions, and threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” (internal quotation marks omitted) (quoting *Iqbal*, 556 U.S. at 678)). Moreover, “[w]here a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

**B. The Complaint Must Be Dismissed for Failure to Allege Injury**

Section 43(a) of the Lanham Act, under which Plaintiff brings its primary claim, provides:

Any person who ... uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities ... shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). In order to survive a motion to dismiss on a Lanham Act false advertising claim, a plaintiff must adequately allege that the challenged misrepresentations are (i) “either literally or impliedly false”; (ii) “material”; (iii) “placed in interstate commerce”; and (iv) “the cause of actual or likely injury to the plaintiff.” See *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 65 (2d Cir. 2016) (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255-56 (2d Cir. 2014)). Defendant argues that none of the alleged misrepresentations in the Complaint is actionable, and therefore the Complaint should be dismissed. (See Def. Br. 13-18). While the Court may quibble as to the relevant strength of Defendant’s arguments with respect to each of the alleged misrepresentations, the Court need not address that part of Defendant’s motion because it finds that Plaintiff has failed to plausibly allege injury.

“[A] plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant’s advertising.” *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133 (2014). Therefore, “a plaintiff in a false-advertising case must demonstrate injury by way of lost sales or damage to business reputation.” *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 394 F. Supp. 3d 368, 374 (S.D.N.Y. 2019). However, “[u]nder Second Circuit authority, the threshold required to show injury differs based on the nature of the advertisements and the parties’ roles as competitors.” *Dependable Sales & Servs., Inc. v. TrueCar, Inc.*, 377 F. Supp. 3d 337, 346 (S.D.N.Y. 2019).

In cases where the challenged advertisement makes a misleading or false comparison to a specific, competing product, “injury may be presumed,” *Merck*, 760 F.3d at 259, because such a comparison “necessarily diminishes that product’s value in the minds of the consumer,” *McNeilab, Inc. v. Am. Home Prods. Corp.*, 848 F.2d 34, 38 (2d Cir. 1988). Therefore, there is no “concern of awarding damages for merely speculative injury.” *Merck*, 760 F.3d at 259. By contrast, where the allegedly misleading advertisement “tout[s] the benefits of the products advertised but ma[kes] no direct reference to any competitor’s products[,] ... some indication of actual injury and causation” is necessary “to ensure that a plaintiff’s injury [is] not speculative.” *McNeilab*, 848 F.2d at 38. This is because “injury in such cases accrues equally to all competitors; none is more likely to suffer from the offending broadcasts than any other.” *Id.*

Defendant argues that Plaintiff has failed to plausibly allege any actual injury (*see* Def. Reply 2-3), and the Court agrees. While it may be that a plaintiff does not need to name specific lost customers in its complaint (*see* Pl. Opp. 16), the Second Circuit has been clear that “some indication of actual injury” is needed for a Lanham Act claim to survive a motion to dismiss, *see McNeilab*, 848 F.2d at 38. And while Plaintiff has alleged that, in the absence of Defendant’s misrepresentations, “more consumers would purchase the Lumin” (Compl. ¶ 171), and that it has been “injured ... in terms of declining sales, lost profits, loss of goodwill, and other injuries” (*id.* at ¶ 185), these allegations are entirely conclusory. *See Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 544 (S.D.N.Y. 2018) (characterizing allegations that the defendant’s

“deceptive and misleading endorsements ... caused Plaintiff ... to lose fees and suffer reputational damage,” and that the defendant’s “conduct ha[d] caused them many million dollars in lost legal business,” as conclusory).

Indeed, completely absent from the Complaint is any allegation of injury that is not speculative in nature. At best, the Complaint provides statements from consumers indicating that they recommend using or prefer using the Lumin because it does not utilize ozone. (See Compl. ¶ 169).<sup>3</sup> These statements, however, do not indicate in any way that Plaintiff has been injured by Defendant’s alleged misrepresentations. If anything, these statements indicate that Plaintiff has *not* been injured, since they are from consumers who have, in fact, purchased Plaintiff’s devices. At most, the statements could be said to support § 1125(a)’s causation requirement, but that requirement is distinct from the need to show actual injury. See *McNeilab*, 848 F.2d at 38 (explaining that plaintiffs must show “some indication of actual injury *and* causation” (emphasis added)).

Plaintiff’s allegations, therefore, fail to meet the Second Circuit’s standards for § 1125(a) actions, see *Merck*, 760 F.3d at 259, and the Supreme Court’s general plausibility standards, see *Twombly*, 550 U.S. at 570. And insofar as Plaintiff believes that *Lexmark* established a more relaxed pleading

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<sup>3</sup> The following is a representative example: “I owned a So Clean cleaner and because of the ozone I developed a rash around my nose and chin that would itch. I contacted So Clean and they told me to use wipes and I did but the problem persisted. I also read that the ozone itself was very bad for respiratory conditions such as COPD of which I have. Do the research. I would no[t] recommend the So Clean device for these reasons. I decided to try Lumin. No Ozone.” (Compl. ¶ 169).

standard for § 1125(a) actions than that articulated by the Second Circuit (*see* Pl. Opp. 16), Plaintiff is incorrect. The “zone of interests” analysis in *Lexmark* identifies who is a proper plaintiff under § 1125(a) — it says nothing about what a plaintiff must do to meet the pleading threshold required by § 1125(a), *Iqbal*, and *Twombly*. *See Lexmark*, 572 U.S. at 129.

If the Court were to take Plaintiff at its word, the Court’s finding that Plaintiff has failed to plead actual injury would end the inquiry. This is because Plaintiff has expressly advised the Court that its Complaint “is not relying on any ... presumption [of injury].” (Pl. Opp. 19). However, the Court believes it proper to address Defendant’s argument that the presumption of injury should not apply in this case. (*See* Def. Br. 11).

As the Court has already noted, the presumption of injury typically only applies in cases where the defendant’s advertisement makes a misleading or false comparison to the plaintiff’s product. *See Merck*, 760 F.3d at 259. And while the Second Circuit “has expressly disfavored presumptions of harm in cases where the products are not obviously in competition or where the defendant’s advertisements make no direct reference to any competitor’s products,” *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 696 (2d Cir. 1994), the Second Circuit has applied or permitted the presumption in certain discrete instances where there is a non-comparative advertisement.

Specifically, those two instances are *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144 (2d Cir. 2007), and *Merck*. In the former case, the Second Circuit held that the presumption was appropriate because the defendant’s

advertisement explicitly disparaged cable television, and plaintiff was the only cable provider in the area. *See Time Warner*, 497 F.3d at 162. Thus, even though the plaintiff was not identified by name, “consumers in the markets covered ... would undoubtedly understand [the] derogatory statement ... as referring to TWC.” *Id.* In *Merck*, the Second Circuit established the limited holding that where “a plaintiff has met its burden of proving deliberate deception in the context of a two-player market, it is appropriate to utilize a presumption of injury.” 760 F.3d at 260-61.

Neither *Time Warner* nor *Merck* applies to the instant action. Unlike *Time Warner*, Defendant’s advertisements and other marketing materials do not implicitly reference or denigrate Plaintiff’s products. And unlike *Merck*, the parties are not operating in a two-player market. Indeed, the Complaint acknowledges both that there are at least three other market participants (*see* Compl. ¶ 161), and that there are individuals who choose to handwash their CPAP equipment instead of investing in the parties’ devices (*see id.* at ¶ 22). Therefore, it would seem that the presumption of injury is inapplicable here. Plaintiff, however, points the Court to *Church & Dwight* (*see* Pl. Opp. 20), in which the Second Circuit, in a footnote that cited to *Merck*, indicated that the presumption might be applicable where the parties “are direct competitors in a sparsely populated market,” 843 F.3d at 72 n.12. This footnote, of course, is *dicta*. Given that the Second Circuit did not, in fact, rely on the presumption of injury in finding that the plaintiff had demonstrated injury in *Church & Dwight*, and given that the Second Circuit “has expressly disfavored presumptions of

harm” except in certain limited circumstances, *Ortho Pharm. Corp.*, 32 F.3d at 696, the Court does not believe it appropriate to extend the presumption to a situation that has not been recognized by the Second Circuit.

The Court also believes that there are sound reasons counseling against application of the presumption in this case. In *Merck*, the Second Circuit held application of the presumption appropriate in a situation where the plaintiff had created the market for its product and then the defendant entered with a competing, falsely labeled product that cost significantly less than the plaintiff’s original product. See 760 F.3d at 260-61. In such a scenario, it makes perfect sense to apply the presumption of injury, since the falsely labeled product was clearly targeted at diverting consumers away from the plaintiff’s product. Here, on the other hand, Defendant is the original entrant into the market, while Plaintiff is the upstart competitor who is seeking to gain market share at Defendant’s expense. Moreover, there are at least three other players in the market — none of which is affiliated with Defendant<sup>4</sup> — and some portion of CPAP users who choose to use no device and handwash their equipment instead. Given that topography, there is no basis upon which the Court can presume, as the Second Circuit could in *Merck*, that Plaintiff’s misrepresentations are targeted at diverting consumers away from the Lumin or its associated devices. Indeed, to allow the presumption in this context would incentivize any upstart competitor in a market to claim, without proof,

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<sup>4</sup> This situation is contrasted with the marketplace in *Church & Dwight*, where the other players in the market were manufactured by a co-owner of the defendant. See 843 F.3d 48, 72 n.12 (2d Cir. 2016).

that a dominant player's long-time marketing statements are causing injury. The Court does not believe this to be a proper use of the presumption, and therefore declines to apply it here.

In the absence of any presumption of injury or an allegation of actual injury, Plaintiff's Lanham Act claim cannot survive. And as Plaintiff itself notes, its state-law claims are largely derivative of its Lanham Act claim. (See Pl. Opp. 20-21). Therefore, Plaintiff's failure to allege injury is likewise fatal to its state-law claims. See *Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 239-40 (S.D.N.Y. 2020) (noting that an element for GBL §§ 349 and 350 claims is that a plaintiff must have "suffered injury as a result of the allegedly deceptive act or practice"); *Chanel, Inc. v. RealReal, Inc.*, — F. Supp. 3d —, No. 18 Civ. 10626 (VSB), 2020 WL 1503422, at \*14 (S.D.N.Y. Mar. 30, 2020) ("The same standards that govern a Lanham Act claim apply to a claim of unfair competition under New York common law, 'except common law requires a showing of bad faith or intent.'" (quoting *BBK Tobacco & Foods, LLP v. Galaxy VI Corp.*, 408 F. Supp. 3d 508, 522 (S.D.N.Y. 2019))). Plaintiff's Complaint is dismissed, and the Court does not reach Defendant's arguments regarding whether or not the alleged misrepresentations are actionable.

### **CONCLUSION**

For the reasons stated in this Opinion, Defendant's motion to dismiss is GRANTED. The Clerk of Court is directed to terminate all pending motions, adjourn all remaining dates, and close this case.

SO ORDERED.

Dated: September 8, 2020  
New York, New York

A handwritten signature in blue ink, reading "Katherine Polk Failla".

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KATHERINE POLK FAILLA  
United States District Judge